K062082

Summary of Safety and Effectiveness

Submitted by: CONMED Electrosurgery Division
14603 East Fremont Avenue
Centennial, CO 80112 USA
Telephone: 303-269-8224
Facsimile: 303-699-9854

Contact Person: Shawn Riedel

JAN 23 2007

Date Prepared: July 19, 2006

Proprietary Name: CONMED ABC Dissecting Electrodes

Common Name: Electrosurgical Electrode

Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
21 CFR 878.4400
79 GEI

Predicate Device: Valleylab Force Argon™ II Argon Enhanced Electrosurgical System
K964636, cleared March 11, 1997

Device Description: The ABC Dissecting Electrodes are electrodes used in conjunction with an Argon Beam Coagulation generator. The system is designed to provide a controlled flow of argon to electrosurgical handsets. The handsets allow the clinicians to perform argon enhanced Electrosurgery in open and laproscopic procedures. The electrodes attach to several previously cleared ConMed Electrosurgery ABC® hand pieces to convert from Argon Beam Coagulation only to Argon Beam Dissect.

When cutting, the edge of the electrode shall be in contact with the tissue while being enclosed in an envelope of argon gas. The electrosurgical energy is passed through the electrode as it is drawn across the tissue. When coagulating, the accessory electrode is not in contact with the tissue and is separated from the tissue by distance for fulguration to achieve the desired result. The electrodes utilizes previously cleared/marketed generators and hand pieces.

Argon Beam Coagulation (ABC)
Argon Beam Coagulation was developed to satisfy a need for a more even spray coagulation effect. With normal electrosurgery spray coagulation may over coagulate and carbonize some areas and under coagulate others due to the randomness of the arcing process. With ABC technology the RF current is focused in a directional, non-contacting, room temperature beam of argon gas. The RF current follows the argon beam from the ABC unit to the patient's tissue and forms a reticulum of arc tunnels which are smaller, more numerous, more uniform size and depth, and more evenly distributed on the tissue. The advantages are faster hemostasis, more homogenous eschar, less tissue damage, and enhanced healing ability. The flow of argon gas also serves to clear the surgical site of fluids allowing direct coagulation on the stroma of the target tissue and reduces carbonization of the tissue to prevent floating eschar.

The sterile disposable electrodes allow the clinician the capability of using their existing hand pieces while being able to exchange the electrodes based on the clinician's desire and need – clinical coagulation or cutting.

Intended Use of Device: Sterile, singe-use electrosurgical accessory used in conjunction with Argon Beam Coagulation generator for delivery of argon gas and electrosurgical current to achieve cutting and coagulation of tissue.

Technological Characteristics: The proposed device is equivalent to the identified predicate device with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of ANSI/AAMI American National Standard for Electrosurgical Devices HF-18, the International Electrotechnical Commission Standard for Electrosurgical Devices, 60601-2-2, Risk Management ISO 14971 and Biocompatibility ISO 10993.

- There are no changes to the generator and therefore no changes to the accompanying software.
- The operator controls the use of the device;
- The generator provides alarms for conditions that could pose a risk to the patient;
- The operator sets the appropriate mode and output settings for the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Conmed Corporation
% Mr. Shawn Riedel
Vice President, Quality Assurance
and Regulatory Affairs
14603 E. Fremont Avenue
Centennial, Colorado 80112

JAN 25 2007

Re: K062082
Trade/Device Name: CONMED ABC® Hip Stem
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: BEI
Dated: November 27, 2006
Received: November 29, 2006

Dear Mr. Riedel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062082

Indications for Use

510(k) Number (if known):
K062082

JAN 25 2007

Device Name:
CONMED ABC® Dissect Electrodes™

Indications for Use:

Sterile, singe-use electrosurgical accessory used in conjunction with Argon Beam Coagulation generator for delivery of argon gas and electrosurgical current to achieve cutting and coagulation of tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062082